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Dockets Management Branch (HFA-305),
Food and Drug Administration
5630 Fishers Lane,
Room 1061
Rockville,
MD 20852

25 June, 2002

Dear Sir/Madam

Re: Comments on the "Draft Guidance for Industry 21CFR Part 11; Electronic Records; Electronic Signatures Time stamps"

Please find below Eurotherm's comments on the " Draft Guidance for industry 21 CFR Part 11; Electronic Records; Electronic Signatures Time Stamps".

1. Timestamp accuracy should be documented as part of the system.
2. If time synchronization is configured as an automatic process then failures to receive time synchronization events at the expected frequency must be recorded in the audit trail - for instance if the time server becomes unavailable.
3. When using an automated time synchronization method the system should track that time synchronization times are within acceptable bounds. If time is out by more than the documented accuracy of the system on receipt of a time sync message then this should be recorded in the audit trail. This ensures that network latencies or clock drift don't allow errors of more than a known magnitude to occur.
4. Inappropriate changes to computer clocks must be detected. Standard Operating Procedure's must be in place to detect and deter inappropriate changes to computer clock."

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I hope you find the above comments useful. If you have any queries please don't hesitate to contact me.

Yours Sincerely,

A handwritten signature in black ink that reads 'Matt Safi'.

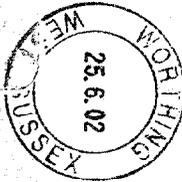
Matt Safi
Pharmaceutical Marketing Manager

AIR MAIL



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